K120507 (1/3)

MAY - 4 2012

510(k) Summary of Safety and Effectiveness

Submitted by:	United Orthopedic Corporation
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Date of Summary:	February 17, 2012
Contact Person	Fang-Yuan Ho Regulation and Document Management
Proprietary Name:	U2 Femoral Component, PS, #7
Common Name:	Knee Prosthesis
Device Classification Name and Reference:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis under 21CFR 888.3560 This falls under the Orthopedics panel.
Device Class	Class II
Panel Code	Orthopaedics Device
Device Product Code:	JWH
Predicate Device:	1. "UNITED" U2 Total Knee System (K051640) 2. "Wright Medical Technology" Advance® Total Knee System (K972626) 3. " Smith & Nephew" Genesis II Knee System (K951987)

Device Description:

This device is an additional size extension to the previously cleared "UNITED" U2 Total Knee System (K051640). The materials, design, safety and effectiveness of this subject is identical to the previously cleared femoral components – PS type of "UNITED" U2 Total Knee System (available in sizes #1~#6 ranging from 52mm/

56mm AP-ML to 72mm/ 76mm A/P-M/L), except for its larger size (76mm/80mm A/P-M/L). This device machined from cast Co-Cr-Mo alloy conforming to ASTM F75 are available in left and right configurations. Fixation of the femoral component to the femur is achieved using bone cement. This device is intended to be used with the previously cleared U2 PS tibial insert (K051640), U2 XPE tibial inserts – PS type (K112463), U2 tibial baseplate (K051640), U2 Patella components (K051640, K082469) and U2 XPE Patella components (K112463) in any size. The size extending of femoral component does not affect the intended use of the device or alter the fundamental scientific technology of the device.

Intended Use

This device is indicated in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities. This device may also be indicated in the salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery.

This device is intended for cemented use only.

Basis for Substantial Equivalence:

The safety and effectiveness of the subject device are substantially equivalent to the previously cleared U2 Total Knee System (K051640), except for an extension in the size distribution. The modifications do not change the intended use or fundamental scientific technology. In addition, the subject device is also substantial equivalence to

the PS femoral components of "Wright Medical Technology" Advance® Total Knee System (K972626) and "Smith & Nephew" Genesis II Knee System (K951987).

Performance Data:

Range of motion analysis, fatigue test, subluxation of femorotibial joint evaluation, contact area and contact pressure analysis on femoropatellar and femorotibial joints and femoral component fatigue fracture evaluation, completed as part of the design assurance process, demonstrated that this device is safe and effective and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

United Orthopedic Corporation
% Ms. Fang-Yuan Ho
No. 57, Park Avenue 2, Science Park
Hsinchu, Taiwan 300

MAY - 4 2012

Re: K120507
Trade/Device Name: U2 Femoral Component, PS, #7
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prothesis
Regulatory Class: Class II
Product Code: JWH
Dated: April 6, 2012
Received: April 9, 2012

Dear Ms. Ho:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510 (k) Number (if known): K120507

Device Name: U2 Femoral Component, PS, #7

Indications for Use:

This device is indicated in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities. This device may also be indicated in the salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery.

This device is intended for cemented use only

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120507